DRAFT PANEL QUESTIONS
12/7/99

1. Are there sufficient data demonstrating an association between vaginal pH and various states of vaginal disease to allow use of such product in an over-the-counter (OTC) setting? If not, what additional studies would be needed?

2. What intended uses are appropriate for an OTC product for measurement of vaginal pH? Two possibilities are as follows:

   a. To monitor for recurrence in a female with a history of documented recurrent vaginal infections
   b. For use in a symptomatic female to determine pH to distinguish between alkaline and non-alkaline vaginal infections
      1. If non-alkaline, to direct use of antifungal creams
      2. If either alkaline or non-alkaline, recommend that they see their doctor

   Should the device be used with pregnant women?

3. FDA recommends use of consumer studies designed to mimic real world use to demonstrate performance in the hands of lay users. FDA suggests that these studies be done in a population representative of the population likely to purchase the device and one that includes individuals from a wide variety of backgrounds. The consumers should use the device without oversight or prior training by a professional.

   Would such a study be sufficient to validate that the device can be performed correctly and the results accurately interpreted? Would focus group testing be needed to ensure the labeling is adequate for use?

4. What labeling is appropriate for such devices?

   a. How should the performance be captured in the labeling?
   b. What limitations should be included in the labeling?
   c. Should the labeling be written similar to an educational brochure?

5. What risks are associated with having these devices available OTC? Do the benefits of OTC use outweigh the risks?